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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/714,166	
	Filing Date	November 14, 2003	
	First Named Inventor	Luigi COLOMBO	
	Art Unit	Not Yet Assigned	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	208 PAGES + 145 REFS.	Attorney Docket Number	342312005200

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement (3 pages) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <ul style="list-style-type: none"><li>• Form PTO-1449 + duplicate copy (22 pages)</li><li>• Co-pending application Serial No. 10/714,261 by M. Cavaleri et al., filed November 14, 2003 (96 pages)</li><li>• Co-pending application Serial No. 10/713,924 by M. Cavaleri et al., filed November 14, 2003 (84 pages)</li><li>• Two Reference Cover Sheets (2 pages)</li><li>• One hundred forty-five (145) references</li><li>• Return postcard</li></ul>
<b>Remarks</b>		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	MORRISON & FOERSTER LLP (Customer No. 25226) Eric H. Witt - 44,408
Signature	
Date	January 12, 2004

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 1/12/04 Signature: Julie M. Hassell



PATENT  
Docket No. 342312005200

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Julie M. Hassell

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Luigi COLOMBO et al.

Serial No.: 10/714,166

Filing Date: November 14, 2003

For: DALBAVANCIN COMPOSITIONS FOR  
TREATMENT OF BACTERIAL  
INFECTIONS

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Pursuant to the USPTO notice dated July 11, 2003, waiving the requirement under 37 C.F.R. § 1.98 (a)(2)(i) to provide copies of U.S. Patents and U.S. Published Applications, copies of those references numbered 1 through 23 are not submitted. Copies of foreign patent documents and non-patent literature are submitted herewith in accordance with 37 C.F.R. § 1.98 (a)(2). The Examiner is requested to make these documents of record.



Applicants would like to draw Examiner's attention to the co-pending applications (copies attached) listed below:

Application Serial No.: 10/714,261 by M. Cavaleri et al., filed November 14, 2003, and

Application Serial No.: 10/713,924 by M. Cavaleri et al., filed November 14, 2003.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97(e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97(e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \_\_\_ is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17(p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 342312005200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 12, 2004

Respectfully submitted,

By: 

Eric Witt

Registration No. 44,408

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Form PTO-1449

Docket Number 342312005200

Application Number 10/714,166

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

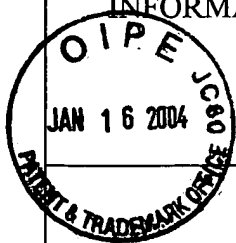
Applicant

Luigi COLOMBO et al.

Filing Date November 14, 2003

Group Art Unit Not Yet Assigned

Mailing Date January 12, 2004



## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	03/25/1980	4,195,079	Celmer et al.			
	2.	12/16/1980	4,239,751	Coronelli et al.			
	3.	09/17/1985	4,542,018	Borghi et al.			
	4.	04/28/1987	4,661,470	Malabarba et al.			
	5.	11/01/1988	4,782,042	Selva et al.			
	6.	09/19/1989	4,868,171	Selva et al.			
	7.	11/21/1989	4,882,313	Sitrin			
	8.	04/03/1990	4,914,187	Malabarba et al.			
	9.	06/19/1990	4,935,238	Selva et al.			
	10.	09/04/1990	4,954,483	Malabarba et al.			
	11.	07/09/1991	5,030,619	Hector			
	12.	11/12/1991	5,064,811	Borghi et al.			
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	19.	08/10/1999	5,935,238	Talcott et al.			
	20.	12/28/1999	6,008,225	Lociuro et al.			
	21.	11/07/2000	6,143,739	Lociuro et al.			
	22.	04/17/2001	6,218,505	Panzone et al.			
	23.	05/07/2002	6,384,013	Burkhardt et al.			

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Application Number 10/714,166

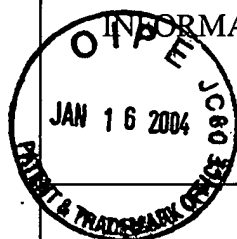
Applicant

Luigi COLOMBO et al.

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Group Art Unit Not Yet Assigned

Mailing Date January 12, 2004

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation	
							YES	NO
	24.	02/16/1983	EP 0 071 970	Europe				
	25.	11/30/1983	EP 0 095 154	Europe				
	26.	04/16/1986	EP 0 177 882	Europe				
	27.	12/10/1986	EP 0 204 179	Europe				
	28.	07/08/1987	EP 0 228 015	Europe				
	29.	10/14/1987	EP 0 240 609	Europe				
	30.	03/16/1988	EP 0 259 781	Europe				
	31.	02/01/1989	EP 0 301 785	Europe				
	32.	05/24/1989	EP 0 316 712	Europe				
	33.	07/04/1990	EP 0 376 041	Europe				
	34.	02/03/1993	EP 0 525 499	Europe				
	35.	10/15/1997	EP 0 801 075	Europe				
	36.	07/28/1999	EP 0 931 834	Europe				
	37.	12/21/1983	GB 2 121 401	Great Britain				
	38.	02/15/1984	GB 2 142 234	Great Britain				
	39.	02/01/1989	JP 1050900	Japan			Abstract	
	40.	04/21/1988	WO 88/02755	WIPO				
	41.	10/04/1990	WO 90/11300	WIPO				

## OTHER DOCUMENTS

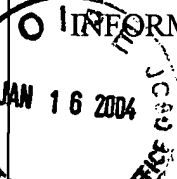
(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	42.	Abramson, M.A. and Sexton, D.J. (1999). "Nosocomial Methicillin-Resistant and Methicillin-Susceptible <i>Staphylococcus Aureus</i> Primary Bacteremia: At What Costs?" <i>Infect. Control Hosp. Epidemiol.</i> 20(6): 408-411.
	43.	Adamczyk, M. et al. (1999). "Investigations Into Self-Association of Vancomycin Covalent Dimers Using Surface Plasmon Resonance Technology," <i>Bioorganic &amp; Medicinal Chemistry Letters</i> 9:2437-2440.

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Form PTO-1449	Docket Number 342312005200	Application Number 10/714,166
 <p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)</p>	Applicant Luigi COLOMBO et al.	
	Filing Date November 14, 2003	Group Art Unit Not Yet Assigned
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44.	Ahrendt, K.A. et al. (2003). "Identification of Potent and Broad-Spectrum Antibiotics from SAR Studies of a Synthetic Vancomycin Analogue," <i>Bioorganic &amp; Medicinal Chemistry Letters</i> 13:1683-1686.
45.	Allen, N.E. and Nicas, T.I. (2003). "Mechanism of Action of Oritavancin and Related Glycopeptide Antibiotics," <i>FEMS Microbiology Reviews</i> 26:511-532.
46.	Anderegg, T.R. et al. (2003). "Initial Quality Control Evaluations for Susceptibility Testing of Dalbavancin (BI397), an Investigational Glycopeptide with Potent Gram-Positive Activity," <i>J. Clin. Microbiol.</i> 41(6): 2795-2796.
47.	Anderegg, T.R. et al. (2003). "Multicenter Quality Control Evaluation Results for Dalbavancin (BI 397), An Investigational Glycopeptide with Potent Gram-Positive Activity," <i>ASM May 2003, Poster No. A-090</i> , one page.
48.	Arimoto, H. et al. (1999). "Multi-Valent Polymer of Vancomycin: Enhanced Antibacterial Activity Against VRE," <i>Chem. Commun.</i> 1999:1361-1362.
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50.	Arioli, V. et al. (1976). "Gardimycin, A New Antibiotic From <i>Actinoplanes</i> : III. Biological Properties," <i>Journal of Antibiotics</i> 29(5):511-515.
51.	Arthur, M. and Courvalin, P. (1993). "Genetics and Mechanisms of Glycopeptide Resistance in Enterococci," <i>Antimicrobial Agents and Chemotherapy</i> 37(8):1563-1571.
52.	Author unknown. (2001). "Dalbavancin tested for soft tissue infections," located at < <a href="http://www.qxhealth.com/news_archieve/cfml/search_details.cfm?sum_ID=8777">http://www.qxhealth.com/news_archieve/cfml/search_details.cfm?sum_ID=8777</a> > last visited on September 8, 2003, one page.
53.	Author unknown. (2000). "Molecule of the Month V-Glycopeptide," located at < <a href="http://www.prous.com/mom/nov_00/mom.html">http://www.prous.com/mom/nov_00/mom.html</a> > last visited on August 27, 2002, two pages.
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55.	Author unknown. (2002). "Treatment Hope for Bloodstream Infections Introduced in Five Percent of Intravenous Catheter Cases," <i>www.biosearch.it</i> , one page.
56.	Barna, J.C.J. and Williams, D.H. (1984). "The Structure and Mode of Action of Glycopeptide Antibiotics of the Vancomycin Group," <i>Ann. Rev. Microbiol.</i> 38:339-357.
57.	Biavasco, F. et al. (2000). "Glycopeptide Susceptibility Profiles of <i>Staphylococcus Haemolyticus</i> Bloodstream Isolates," <i>Antimicrobial Agents and Chemotherapy</i> 44(11): 3122-3126.
58.	Campbell, K.C.M. et al. (2003). "Audiologic Monitoring for Potential Ototoxicity in a Phase I Clinical Trial of a New Glycopeptide Antibiotic," <i>J. Amer. Acad. Audiology.</i> 14(3):157-168.
59.	Candiani, G. et al. (1999). "In-Vitro and In-Vivo Antibacterial Activity of BI 397, a New Semi-Synthetic Glycopeptide Antibiotic," <i>J. Antimicrob. Chemother.</i> 44:179-192.

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| 60. | Cavaleri, M. et al. (2002). "Protein Binding of Dalbavancin Using Isothermal Titration Microcalorimetry," <i>42nd ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1385, pg. 18.                       |
| 61. | Cavaleri, M. et al. (2002). "Protein Binding of Dalbavancin Using Isothermal Titration Microcalorimetry," <i>42nd ICAAC</i> , San Diego, CA, September 27-30, 2002. <b>Poster No. A-1385</b> , one page.                         |
| 62. | Chaix, C. et al. (1999). "Control of Endemic Methicillin-Resistant <i>Staphylococcus Aureus</i> ," <i>JAMA</i> 282(18):1745-1751.  |
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| 64. | Darouiche, R.O. and Mansouri, D.M. (Date Unknown). "Dalbavancin Versus Vancomycin for Prevention of <i>Staphylococcus aureus</i> Colonization of Devices in an Animal Model," <b>Poster #174</b> , one page.                     |
| 65. | Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," <i>Abstracts of the IDSA 40th Annual Meeting</i> , October 24 - 27, 2002. Abstract No. 52, pg. 53.                |
| 66. | Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," <i>Abstracts of the IDSA 40th Annual Meeting</i> , October 24 - 27, 2002. <b>Poster No. 52</b> , one page.        |
| 67. | Dowell, J. et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," <i>ECCMID: Clinical Microbiology and Infection</i> , Abstract No. P1224. Vol. 9(Supp. 1), p. 291.               |
| 68. | Dowell, J. et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," <i>ECCMID: Clinical Microbiology and Infection</i> , <b>Poster No. P1224</b> , one page.                        |
| 69. | Dowell, J.A. et al. (2002). "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," <i>42 ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1386, pg. 18.                        |
| 70. | Dowell, J.A. et al. (2002). "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," <i>42 ICAAC</i> , San Diego, CA, September 27-30, 2002. <b>Poster No. A-1386</b> , one page.                          |
| 71. | Dowell, J.A. et al. (2003). "Dalbavancin (DAL) Pharmacokinetics (PK) in Subjects With Mild or Moderate Hepatic Impairment (HI)," <i>43rd. Annual ICAAC</i> , Chicago, IL, September 14-17, 2003. <b>Poster #A-19</b> , one page. |
| 72. | Ednie, L. et al. (2003). "Antistaphylococcal Activity of Dalbavancin Compared to Those of Six Other Agents," <i>43rd. Annual ICAAC</i> , Chicago, IL, September 14-17, 2003, <b>Poster #C1-1631</b> , one page.                  |
| 73. | Fieser, L.F. and Fieser, M. (1967). <i>Reagents for Organic Synthesis</i> John Wiley and Sons, Inc. pp. 128-130.   |

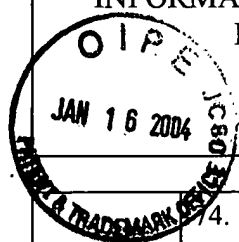
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74.	Fridkin, S.K. et al. (2003). "Epidemiological and Microbiological Characterization of Infections Caused by Staphylococcus Aureus with Reduced Susceptibility to Vancomycin, United States, 1997-2001," <i>Clinical Infectious Diseases</i> 2003 36: 429-439.		
75.	Ge, M. et al. (1999). "Vancomycin Derivatives That Inhibit Peptidoglycan Biosynthesis Without Binding D-Ala-D-Ala," <i>Science</i> 284:507-511.		
76.	Goldstein, B.P. et al. (1994). "Comparative Antibacterial Activity of Semi-Synthetic Derivatives of the Glycopeptide Antibiotic A40926 (MDL 62,476)," <i>Abstracts of the 34th ICAAC</i> Orlando FL October 4-7, 1994 Abstract No. F142 pg. 225.		
77.	Goldstein, D. (May 10, 2001). "Versicor, Inc. Will Host Conference Call to Discuss Advanced Clinical Development Programs For Lead Antifungal and Antibiotic Products." Press Release, two pages.		
78.	Goldstein, D. and Halsey, K. (November 28, 2001). "Versicor Announces Plans to Develop Dalbavancin As The First Once-Weekly Injectable Antibiotic." Press Release, three pages.		
79.	Goldstein, D. and Halsey, K. (December 17, 2001). "Versicor Announces Data Demonstrating Tolerability of Anidulafungin at Higher Doses." Press Release, three pages.		
80.	Goldstein, D. and Halsey, K. (March 12, 2002). "Versicor Announces Start of Phase II Study of Once-Weekly Dalbavancin for Bloodstream Infections." Press Release, three pages.		
81.	Goldstein, D. and Halsey, K. (May 21, 2002). "Versicor Announces Completion of Phase II Study of Once-Weekly Dalbavancin for Skin and Soft Tissue Infections." Press Release, three pages.		
82.	Goldstein, D. et al. (May 22, 2001). "Versicor Begins Phase II Trial of Dalbavancin, Its Noval Glycopeptide Antibiotic." Press Release, three pages.		
83.	Goldstein, D. et al. (December 17, 2001). "Versicor Announces Positive Phase I Data for Dalbavancin, Demonstrating Feasability of Once-Weekly Dosing." Press Release, four pages.		
84.	Goldstein, D. et al. (September 5, 2002). "Versicor Announces Positive Phase 2 Study Results With Dalbavancin For Skin and Soft Tissue Infections." Press Release, three pages.		
85.	Goldstein, D. et al. (September 19, 2002). "Versicor Announces 24 Abstracts to be Presented at Annual ICAAC Meeting Next Week." Press Release, three pages.		
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88.	Goldstein, E.J.C. and Citron, D.M. (2002). "In Vitro Activities of Dalbavancin and Nine Comparator Agents against Fastidious and Anaerobic Gram-Positive Species," <i>42nd ICAAC Abstracts</i> , San Diego, CA, September 27 - 30, 2002. Abstract No. E-1454, pg. 163.		
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89.	Goldstein, E.J.C. et al. (2003). "In Vitro Activities of Dalbavancin and Nine Comparator Agents against Anaerobic Gram-Positive Species and Corynebacteria," <i>Antimicrob. Agents and Chemother.</i> 47(6): 1968-1971.		
90.	Greene, T. W. (1981). <u>Protective Groups in Organic Synthesis</u> John Wiley and Sons, Inc. pp. ix-x (Table of Contents Only.)		
91.	Griffin, J.H. (2003). "Multivalent Drug Design, Synthesis and In Vitro Analysis of an Array of Vancomycin Dimers," <i>JACS</i> 125:6517-6531.		
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Form PTO-1449

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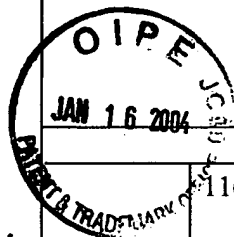
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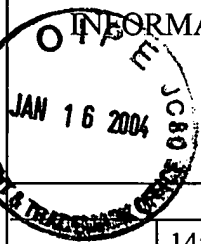
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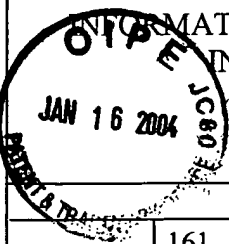
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